IN THE UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

Ethel Kellogg,

Plaintiff,

v.

WYETH, Individually and as Successor-In-Interest to A.H. ROBINS COMPANY, INC. and AMERICAN HOME PRODUCTS CORPORATION; SCHWARZ PHARMA, INC.; ACTAVIS, INC.; ACTAVIS-ELIZABETH, L.L.C.; ALPHARMA, INC.; PUREPAC PHARMACEUTICAL COMPANY, INC.; TEVA PHARMACEUTICALS, USA, INC.; BAR PHARMACEUTICALS, INC.; PLIVA, INC.; and DRUG COMPANY DOES 1 THROUGH 10, inclusive.

Defendants.

CASE NO. 2:07-cv-82

AMENDED COMPLAINT

PLAINTIFF alleges:

PARTIES AND JURISDICTION

1. The Plaintiff, ETHEL KELLOG, is a natural person. She resides at 29 Maple Street, Salisbury, Addison County, Vermont.

2. Plaintiff is informed and believes Defendant WYETH is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at Five Giralda Farms, Madison, New Jersey 07940. Plaintiff is further informed and believes ESI LEDERLE Inc. ("LEDERLE") is a division of WYETH. Plaintiff is further informed and believes that at all times material

hereto, LEDERLE manufactured, distributed or contracted for the manufacture and distribution of a generic form of metoclopramide in the State of Vermont that was identified with an NDC number assigned to LEDERLE and that was ingested by Plaintiff. Plaintiff is further informed and believes that WYETH and LEDERLE are subject to suit in the State of Vermont because at all times relevant to this Complaint, WYETH and LEDERLE regularly conducted business in this State receiving substantial revenues in this State and distributed products in this State which have caused injury to Plaintiff.

3. Plaintiff is informed and believes that at all times material hereto Defendant SCHWARZ PHARMA, INC. ("SCHWARZ PHARMA") was and is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware with its office and principal place of business at 6140 W Executive Drive, Mequon, Ozaukee County, Wisconsin 53092.

4. Plaintiff is informed and believes that at all times material hereto Defendant ACTAVIS GROUP ("ACTAVIS") is an Icelandic corporation with its principal place of business in Hafnarfjordur, Iceland. Plaintiff is further informed and believes that defendant ACTAVIS-ELIZABETH, L.L.C. ("ACTAVIS-ELIZABETH") is a wholly owned subsidiary of defendant ACTAVIS with its principal place of business in Elizabeth, New Jersey. Plaintiff is further informed and believes that defendant ACTAVIS and/or defendant ACTAVIS-ELIZABETH is the successor in interest of defendant ALPHARMA and defendant PUREPAC PHARMACEUTICAL CO., INC. ("PUREPAC"). Plaintiff is further informed and believes that defendant ALPHARMA was and is a Delaware corporation with its principal place of business in Fort Lee, New Jersey. Plaintiff is further informed and believes that defendant PUREPAC was and is a Delaware corporation with its principal place

of business in Cranford, New Jersey. Plaintiff is further informed and believes that defendant PUREPAC manufactured, distributed or contracted for the manufacture and distribution of a generic form of metoclopramide in the State of Vermont that was identified with an NDC number assigned to defendant ALPHARMA and/or defendant PUREPAC PHARMACEUTICAL CO and that was ingested by Plaintiff. Plaintiff is further informed and believes that ALPHARMA and PUREPAC are subject to suit in the State of Vermont because at all times relevant to this Complaint, defendants ALPHARMA and PUREPAC regularly conducted business in this State receiving substantial revenues in this State and distributed products in this State which have caused injury to Plaintiff.

5. Plaintiff is informed and believes that at all times material hereto Defendant TEVA PHARMACEUTICALS USA, INC ("TEVA") was and is a Delaware corporation with its principal place of business in the State of Pennsylvania and is a wholly owned subsidiary of TEVA Pharmaceuticals Industries, Ltd, an Israeli Corporation with its principal place of business in Israel. Plaintiff is further informed and believes that defendant TEVA manufactured, distributed or contracted for the manufacture and distribution of a generic form of metoclopamide in the State of Vermont that was identified with an NDC number assigned to defendant TEVA and that was ingested by Plaintiff. Plaintiff is further informed and believes that defendant TEVA is subject to suit in the State of Vermont because at all times relevant to this Complaint, defendant TEVA regularly conducted business in this State receiving substantial revenues in this State and distributed products in this State which have caused injury to Plaintiff.

6. Plaintiff is informed and believes that at all times material hereto Defendant BAR PHARMACEUTICALS, INC. ("BAR") is a Delaware corporation with its principal

place of business in Pomona, New York, which is the successor in interest to Defendant PLIVA, INC. Plaintiff is further informed and believes that defendant PLIVA, INC. ("PLIVA") is a New Jersey corporation with its principal place of business in East Hanover, New Jersey, and is a wholly owned subsidiary of PLIVA d.d., a Croation corporation with its principal place of business in Zagreb, Croatia. Plaintiff is further informed and believes that defendant PLIVA manufactured, distributed or contracted for the manufacture and distribution of a generic form of metoclopramide in the State of Vermont that was identified with an NDC number assigned to defendant PLIVA and that was ingested by Plaintiff causing her harm. Plaintiff is further informed and believes that defendant PLIVA is subject to suit in the State of Vermont because at all times relevant to this Complaint, defendant PLIVA regularly conducted business in this State receiving substantial revenues in this State and distributed products in this State which have caused injury to Plaintiff.

7. Plaintiff further alleges that Defendants DRUG COMPANY DOES 1 through DOES 10 are companies whose identity is presently unknown to plaintiff who manufactured, distributed or contracted for the manufacture or distribution of a generic form of metoclpramide in the State of Vermont with an NDC number that is presently unknown to Plaintiff but which was ingested by Plaintiff causing her harm. Plaintiff further alleges that DRUG COMPANY DOES 1 through DOES 10 are subject to suit in the State of Vermont because at all times relevant to this Complaint, Defendants DRUG COMPANY DOES 1 through 10 regularly conducted business in this State receiving substantial revenues in this State and distributed products in this State which have caused injury to Plaintiff.

8. In this Complaint, Defendants Wyeth, A. H. Robins Company, Inc., Schwartz-Pharma, Actavis, Actavis-Elizabeth, Alpharma, Purepac, Teva, Pliva and Drug Company Does 1 through 10 are sometimes referred to as the "drug company defendants."

9. Each of the drug company defendants is and has been engaged in the business of designing, developing, testing, manufacturing, marketing, promoting, distributing, and/or selling drug products in the state of Vermont. This Court has personal jurisdiction over each of the defendants because each has the requisite constitutional contacts with the United States of America and with the State of Vermont.

10. The amount in controversy exceeds $75,000, exclusive of interest and costs. Thus, given the complete diversity of the parties, this Court has subject matter jurisdiction over this action pursuant to 28 USC § 1332.

11. Events giving rise to this lawsuit and as alleged in this Complaint occurred in the state of Vermont and in this district. Venue in this district is proper under 28 U.S.C. § 1391.

GENERAL ALLEGATIONS OF FACT

12. Beginning in the 1980s and up to approximately the early part of 2002, defendant Wyeth (and/or its corporate predecessors in interest, including the A.H. Robins Company, Inc., of Virginia) designed, developed, tested, manufactured, distributed, and sold a name brand prescription drug product known as "Reglan," and marketed and promoted the product to physicians as a prescription drug suitable for the treatment of gastroesophogeal reflux disease ("GERD"), diabetic gastroporesis, and other gastrointestinal ailments. Thereafter, defendant Schwarz has manufactured (or caused to be manufactured), marketed, promoted, distributed, and sold Reglan.

13. Reglan contains as its sole active ingredient the drug substance referred to variously as metoclopramide hydrochloride, metoclopramide HCl, or metoclopramide.

14. Defendants Purepac, Teva, and Pliva individually and independently designed, developed, tested, manufactured, promoted, distributed, and/or sold prescription drug products referred to variously as "generic metoclopramide" or "generic for Reglan." In this Complaint, defendants Purepac, Teva, and Pliva are sometimes referred to as the "generic drug company defendants."

15. Each of the generic drug company defendants represented their respective generic metoclopramide products to contain the same sole active ingredient as Reglan and to be bioequivalent and therapeutically equivalent to Reglan. Each of the generic metoclopramide products in fact did have the same sole active ingredient as Reglan and in fact was bioequivalent and therapeutically equivalent to Reglan.

16. The United States Food and Drug Administration ("FDA") and the medical and pharmaceutical communities, including virtually all physicians, pharmacists, and drug companies, recognize and have recognized that bioequivalent and therapeutically equivalent generic drug products should be expected to produce and do produce the same pharmacological and other physiological effects, including side effects, in patients as equivalent doses of their counterpart name brand drug products.

17. Commercial retail pharmacies typically fill prescriptions with generic versions of name brand drugs when a generic version is available. Pursuant to 18 V.S.A. §4605. Alternative drug selection**,** a pharmacist is required or permitted to fill a prescription for a particular drug, whether identified by brand name (such as "Reglan") or by generic name (such as "metoclopramide"), with a cheaper generic version of the drug. Similar laws

(so-called "drug product selection laws") apply, and have applied for decades, in all 50 states and in territories of the United States.

18. All wholesale shipments of prescription drug products, and all samples of such products, are accompanied by "package inserts," which contain information about the product, including its active and inactive ingredients, pharmacokinetics, chemistry, warnings, and side effects. The verbatim content of the package insert, for a name brand prescription drug product, is typically published, at the instance of the manufacturer, as a so-called "monograph" for the product, in the Physician's Desk Reference (PDR), an annual compilation of such monographs, supplemented periodically. A monograph for any prescription drug product may be published in the PDR at the instance of its manufacturer, upon payment of a fee to the publisher.

19. All else being equal, a physician's reliance on the information concerning the properties and effects of a drug or drug product, as contained in the package insert (or PDR monograph) for the drug product, or in other literature, or statements disseminated by the manufacturer of the product, is foreseeable and reasonable, and equally foreseeable and reasonable as to the properties and effects of therapeutically equivalent generic drug products.

20. Each of the generic drug company defendants adopted, in substance, as the text of the "package insert" for its generic metoclopramide product, the verbatim content of the package insert for Reglan, as revised from time to time, modified only to reflect therapeutically non-relevant differences among the products, such as color, shape, inactive ingredients, and source of manufacture.

21. Each of the generic drug company defendants relied upon Wyeth and Schwarz to communicate to physicians adequate information concerning the appropriate uses and risks entailed in the uses of metoclopramide products, including both Reglan and the bioequivalent and therapeutically equivalent generic metoclopramide products, and each impliedly adopted, as applicable to its own generic metoclopramide product, such information as was disseminated about Reglan and/or metoclopramide by defendants Wyeth and Schwarz.

22. At all relevant times, each of the drug company defendants knew or, in the exercise of reasonable care toward patients who would be expected to ingest metoclopramide products, should have known that:

a) Metoclopramide is a neuroleptic drug, classified as such (because of its effects on the central nervous system, specifically as a dopaminergic antagonist) with other neuroleptic drugs, which are also classified as antipsychotic drugs (because of their use in treating schizophrenia), and which are commonly recognized, among internists, family and general practitioners, and gastroenterologists, as leading to a high incidence of tardive dyskinesia and related extrapyramidal symptoms ("EPS") when used for prolonged periods of six months to a year or more.

b) Specific neuroleptic drugs, in the absence of data specific to the drug, are expected to lead to tardive dyskinesia in between 20 and 40 percent of patients who are exposed to the drug in usual therapeutic doses for periods of 6 months to a year or more.

c) The period for clinical trials for Reglan did not exceed three months in duration of exposure to the patients.

d) The results of epidemiological studies, published in peer-reviewed scientific and medical literature, have consistently shown, for many years, a high prevalence of tardive dyskinesia and other EPS among metoclopramide users, particularly those exposed to the drug for prolonged periods.

e) These published epidemiological studies represent the best scientific evidence then available for evaluating the association between metoclopramide exposure and the prevalence or incidence of tardive dyskinesia and other EPS.

f) Gastroesophogeal reflux and diabetic gastroporesis are typically and often experienced chronically or intermittently over long periods of time.

g) Physicians commonly prescribe metoclopramide products, as treatment for gastroesophogeal reflux and/or diabetic gastroporesis, for prolonged periods of six months to a year or more.

23. The package inserts for metoclopramide products, and the PDR monograph for Reglan, contained false and/or misleading statements and omitted information material to the foreseeable and ordinary contemplated uses of the products. These statements and omissions include:

a) The statement that "Like the phenothiazines and related drugs, which are also dopamine antagonists, metoclopramide produces sedation and may produce extrapyramidal reactions, although these are comparatively rare (See WARNINGS)." This statement is false and misleading in light of the manufacturers' knowledge that extrapyramidal reactions are far more common, particularly when metoclopramide is used long-term and their concurrent knowledge that metoclopramide is commonly prescribed for long-term use.

b) The statement that the most common EPS occurred in approximately 1 in 500 hundred patients using metoclopramide. This statement is without scientific evidence of any sort capable of supporting it.

c) The omission of any reference to epidemiological studies and other evidence suggesting that the prevalence of tardive dyskinesia among patients exposed to metoclopramide for six months or longer is as much as 100 times greater than 1 in 500.

d) The statement that use of metoclopramide products for longer than 12 weeks "had not been evaluated" and therefore "cannot" be recommended. The statement misleadingly implies that no evaluation whatever of longer term use has been undertaken, or that use for longer than 12 weeks would be recommended if only formal evaluations or clinical studies for such periods had been performed.

e) The statement that the risk of tardive dyskinesia from exposure to metoclopramide is "believed" to increase with duration of treatment and total cumulative dose. The statement misleadingly implies that the "belief" is not supported, or not strongly supported, by scientific evidence.

f) The omission of any statement that therapy with metoclopramide should not extend beyond three months, which implies, in context, that no scientific evidence suggests, or strongly suggests, that longer term use increases substantially the risks of overexposure.

g) The statement that "Extrapyramidal symptoms, manifested primarily as acute dystonic reactions, occur in approximately 1 in 500 patients treated with the usual adult dosages of 30-40 mg/day of metoclopramide," which tends to understate

concerns about more serious extrapyramidal symptoms such as akathisia and tardive dyskinesia.

24. The dangerous propensities of metoclopramide products, as referenced above, were known or scientifically knowable to the drug company defendants, through appropriate research and testing, at the time they distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients, or their patients.

25. In its dissemination of information to physicians concerning Reglan, Wyeth (and in particular the A. H. Robins Company, Inc. prior to its merger with and into Wyeth) promoted the idea that long-term use of metoclopramide or Reglan was both safe and effective. The promotion of such use included presentations by sales representatives (known as "detail men") emphasizing the drug's gastroenterological effects, in particular gastric emptying, at the expense of its extrapyramidal effects; the sponsoring of talks and seminars with company sponsored speakers, who would discuss the supposed benefits and safety of longer term use; and the ghost-authoring, company-sponsored publication, and further dissemination of at least one junk science study calculated to "demonstrate" the safety of long-term metoclopramide use. Defendants Wyeth and Schwarz have never repudiated the substance of this promotion or acted to neutralize its effects.

26. Between 5/8/00 and 5/24/04, Plaintiff's physicians prescribed "Reglan" and/or "metoclopramide" for the plaintiff as treatment for gastroesophageal reflux disease (GERD).

27. In prescribing the metoclopramide products for the plaintiff as they did, the plaintiff's physicians relied upon the information published in the package inserts and/or the PDR and/or otherwise disseminated by the drug company defendants, in particular the

manufacturer/distributor of the name brand product Reglan, and were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false, and/or otherwise inadequate information thus disseminated.

28. The plaintiff's pharmacists filled the prescriptions with Reglan and/or generic metoclopramide products, as authorized or required by state law, specifically 18 V.S.A. § 4605. Alternative drug selection, which is similar to other so-called "drug product selection laws" enacted in every state.

29. The plaintiff took the metoclopramide products as prescribed continuously from 2000 through at least June 2004.

30. Mrs. Kellogg's use of metoclopramide products, as prescribed, resulted in her overexposure to the drug metoclopramide which caused her to suffer serious, permanent and disabling injuries, including but not limited to injuries of or associated with the central nervous and extrapyramidal motor systems, specifically a tardive dyskinesia syndrome which included oral dystonic facial grimacing and lip twisting chewing type of movements, and intermittent tongue thrusting, uncontrolled pronation of her feet, gait instability, difficulty swallowing and lately, difficulty controlling her hands and arms. Because of these injuries the plaintiff has experienced and will continue to experience medical and related expenses, loss of ability to provide household services for herself, disfigurement, disability, pain and suffering, psychological injury, and other injuries and damages.

31. The plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of the drug company defendants' dissemination to physicians of inaccurate, misleading, materially incomplete, false, and otherwise inadequate

information concerning the potential effects of exposure to metoclopramide and the ingestion of metoclopramide products.

32. Defendant Wyeth (including A.H. Robins Company, Inc., prior to its merger into Wyeth, and as Wyeth thereafter) has marketed Reglan to physicians in a manner calculated to increase sales of the drug and resultant profits to the drug company at the expense of and in conscious disregard for the health and safety of those who, through over-prescription of the drug at excessive dosage and/or for excessive periods of time and/or for patients for whom safer effective alternative treatments existed, consequently develop tardive dyskinesia, akathisia, depression, suicidal ideation, lassitude, weakness and other extrapyramidal symptoms ("EPS").

33. The A.H. Robins Company, Inc., knew that the conditions for which metoclopramide was prescribed, in particular gastroparesis and gastroesophageal reflux, are chronic conditions which indicate, for their treatment, long-term therapy. Despite this knowledge, The A.H. Robins Company, Inc., consciously chose to evaluate the safety and efficacy of the drug through scientific investigation for periods not exceeding 12 weeks.

34. The A.H. Robins Company, Inc. knew that metoclopramide, as a dopamine antagonist and/or a neuroleptic drug, is as likely as other dopamine antagonists and/or other neuroleptic drugs to cause tardive dyskinesia and other EPS, particularly at higher exposures and longer durations of use. Despite this knowledge, the A.H. Robins Company, Inc. consciously sponsored the performance and dissemination of non-scientific investigations to suggest that metoclopramide is safe for long-term use, proposed and distributed labeling suggesting that EPS side effects are rare with metoclopramide use, whether short-term or long-term, and otherwise systematically suppressed or undercut the dissemination of specific

scientific information about the risks and prevalence of side effects associated with Reglan®/metoclopramide to physicians, to the generic metoclopramide industry and to the FDA. Defendant Wyeth knew about the efforts of the A.H. Robins Company, Inc. to promote the long-term safety of Reglan before or shortly after it acquired all of the assets and liabilities of the A.H. Robins Company, Inc. and despite this knowledge, Defendant Wyeth never took any steps to correct the misleading information that had been disseminated by its predecessor, the A.H. Robins Company, Inc.

35. Wyeth knew from its own investigations, including analysis of sales statistics, and from scientific studies published in peer-reviewed medical journals, that many physicians were unaware of the extent of the risks posed by metoclopramide therapy at high dosages and/or long-term exposure, that many physicians were over-prescribing metoclopramide, and that many patients, as a result, developed serious EPS side effects, including depression with suicidal ideation, akathisia, akinesia, tardive dyskinesia and tardive dystonia, who would not have developed these side effects but for their overexposure to Reglan®/metoclopramide. Despite this knowledge, Wyeth consciously failed to make or propose any changes in the metoclopramide labeling and consciously declined to disseminate information to physicians, to the generic metoclopramide industry or to the FDA that would alert them to the fact or risk of metoclopramide exposure.

36. Defendants Schwarz Pharma, Alpharma, Purepac, Teva, Actavis and Pliva knew or should have known about the false and misleading information and the omitted information in the package inserts for metoclopramide and the PDR monograph for Reglan, knew or should have known about the widespread tendency among physicians to prescribe

metoclopramide for long-term use and knew about the substantially increased prevalence of tardive dyskinesia and other serious extrapyramidal side effects of metoclopramide, particularly when it is prescribed for long-term use and, notwithstanding this knowledge, consciously decided to ignore this information, rather than urgently propose new labeling to the FDA or send "Dear Healthcare Practitioner" letters to physicians, in order to warn physicians about the danger associated with long-term use of metoclopramide.

37. In doing the acts alleged in this Complaint, Defendant Wyeth and Defendants Schwarz Phrama, Alpharma, Purepac, Teva, Actavis and Pliva have acted with oppression, fraud, and malice, evincing a willful, wanton, and conscious disregard for the rights, health, and safety of patients, including the plaintiff, who would be expected to be induced, by that conduct, to ingest uwarranted amounts of metoclopramide for prolonged and unwarranted periods of time, leading to grievous, debilitating, and potentially permanent personal injury.

FIRST CAUSE OF ACTION
Negligent Misrepresentation

38. Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

39. Based on public policy, legislative enactments, and customary practices among physicians and manufacturers of generic drug products, defendants Wyeth and Schwarz Pharma knew or ought to have realized that physicians, in weighing the potential benefits and potential risks of using metoclopramide products, whether name brand or generic or either, and in writing prescriptions for either "Reglan" or "metoclopramide," would rely upon information disseminated to them by the manufacturer of the name brand drug product, regardless of whether the prescriptions might be filled with either the name brand product,

Reglan, or generic metoclopramide products, and that many patients, in accordance with those prescriptions, would be likely to ingest generic metoclopramide products.

40. It is the public policy of the United States and of this state, as reflected in the Hatch-Waxman Act and in 18 V.S.A. § 4605. Alternative drug selection, to encourage the availability of cheaper, generic drug products that are therapeutically equivalent to name brand products and to encourage the substitution, as appropriate, of such generic products for name brand products in medical therapy.

41. So-called "drug product selection laws" enacted in every state, including this state (see 18 V.S.A. § 4605. Alternative drug selection), authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limited exceptions, with a generic drug product that is therapeutically equivalent to the name brand drug product.

42. As a custom, the manufacturers and/or distributors of generic drug products typically and simply copy verbatim, for the package inserts for their own products, the therapeutically relevant content of the package insert for the name brand prescription drug product, for which the generic products are therapeutic equivalents; and, further, that the manufacturers of the counterpart generic products typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

43. To obtain basic information about the properties and effects of a drug or drug product that is available in both name brand and generic formulations, physicians have commonly and typically consulted the information disseminated by the manufacturer/distributor of name brand product, in PDR monographs or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their

patients, whether by brand name or generic name. Patients, therefore, are likely to receive and ingest, per those prescriptions, one or more generic products that are therapeutically equivalent to the name brand product.

44. Defendants Wyeth and Schwarz Pharma disseminated to physicians, through package inserts, the publication of a PDR monograph, and otherwise, information concerning the properties and effects of metoclopramide and Reglan, with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

45. Defendants Wyeth and Schwarz Pharma knew or ought to have realized that patients receiving prescriptions for Reglan or generic metoclopramide written in reliance upon information they disseminated as the manufacturer/distributor of Reglan, the name brand metoclopramide product, would be placed in peril of grievous personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

46. DefendantsWyeth and Schwarz Pharma owed a duty in all of its several undertakings, including the dissemination of information concerning metoclopramide and Reglan, to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others.

47. Defendants Wyeth and Schwarz Pharma failed to exercise reasonable care to ensure that the information it disseminated to physicians concerning the properties and

effects of metoclopramide and Reglan was accurate and not misleading. As a result, the information it disseminated to physicians was negligently and materially inaccurate, misleading, and false.

48. As a proximate and foreseeable result of this negligence by Defendants Wyeth and Schwarz Pharma, the plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when her physicians, in reasonable reliance upon the negligently inaccurate, misleading, and false information disseminated by Wyeth and Schwarz Pharma, and believing the information to be true, prescribed for the plaintiff the use of Reglan and/or metoclopramide for a prolonged and unwarranted period of time and she ingested, per those prescriptions, metoclopramide products, leading to her toxic overexposure to metoclopramide.

SECOND CAUSE OF ACTION
Fraud

49. Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

50. Defendants Wyeth (and particularly its corporate predecessor in interest, A. H. Robins Company, prior to its merger with and into Wyeth) and Schwarz Pharma disseminated the false information, as referenced above, to physicians and, indirectly, to their patients, knowing the information to be false or in conscious disregard of whether it was false or not false, with the intention to deceive the physicians, and indirectly their patients, and to induce the physicians to prescribe Reglan and/or other metoclopramide products, and in particular to prescribe Reglan and/or other metoclopramide products for prolonged periods of time.

51. As a foreseeable and proximate result of this knowing dissemination of knowingly and/or recklessly false information, as referenced above, the plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when her physicians, in reasonable reliance upon this false information, and believing the information to be true, prescribed for the plaintiff the use of metoclopramide products for a prolonged and unwarranted period of time and she ingested, per those prescriptions, metoclopramide products, leading to her toxic overexposure to metoclopramide.

THIRD CAUSE OF ACTION
Fraud by Concealment

52. Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

53. Defendants Wyeth (and particularly its corporate predecessor in interest, A. H. Robins Company, prior to its merger with and into Wyeth) and Schwarz Pharma, with the intention of deceiving physicians and their patients, and to induce physicians to prescribe, and their patients to ingest, metoclopramide products for prolonged periods of time, informed physicians, through package inserts and otherwise, that exposure to metoclopramide can lead to tardive dyskinesia and other EPS, that the risk is "believed" to increase with duration of therapy and total cumulative dose, and that therapy for longer than 12 weeks "cannot be recommended," but knowingly concealed from the physicians material facts bearing on the interpretation of those disclosures, including the fact that earlier false information, disseminated by A.H. Robins Company, and representing long term metoclopramide therapy be reasonably safe, was unscientific and false; that metoclopramide is a neuroleptic agent and dopamine antagonist, which can be expected to lead to tardive dyskinesia and other EPS with

approximately the same high frequency, particularly in longer term use, as other neuroleptic drugs; that epidemiological studies have consistently confirmed this expectation; and that the treatment of chronic or intermittent gastroesophogeal reflux or diabetic gastroporesis with metoclopramide and/or metoclopramide products for longer than 12 weeks is unlikely to be reasonably safe.

54. The plaintiff's physicians, in reasonable reliance upon this information, and without knowledge of the undisclosed and knowingly concealed facts, determined that the benefits of prolonged metoclopramide therapy outweighed the risks for their patient, the plaintiff, and prescribed a prolonged course of therapy for her with metoclopramide products.

55. As a proximate and foreseeable result of this knowing and fraudulent concealment of material facts, the plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when her physicians, in reasonable reliance upon the information, and and in ignorance of the facts concealed from them in those disseminations, prescribed for the plaintiff the use of Reglan and/or metoclopramide for a prolonged and unwarranted period of time and she ingested, per those prescriptions, metoclopramide products, leading to her toxic overexposure to metoclopramide.

FOURTH CAUSE OF ACTION
Products Liability - Negligence

56. Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

57. As manufacturers of prescription drug products, specifically metoclopramide products, the drug company defendants owed a duty toward foreseeable users of metocloparamide products, including the plaintiff, to exercise reasonable care to ensure that the metoclopramide products they manufactured and/or distributed were reasonably safe for

their ordinary and intended uses, and specifically, *inter alia*, to ensure through the regular review of published scientific literature regarding their products and periodic evaluation of how their product was actually being used by physicians, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks inherent in such use.

58. Each of the drug company defendants breached its duty toward patients expected to use its metoclopramide products, including the plaintiff, by failing to exercise reasonable care in its labeling of the products for their effects in ordinary and foreseeable uses, including long term use, and in its dissemination to physicians of information concerning the products' effects, and thereby failed, specifically, to communicate to physicians information which was accurate, nonmisleading, and otherwise adequate to enable the physicians to make informed choices concerning the reasonably safe use of the products and to enable physicians to provide accurate and adequate information to their patients about the risks of long-term use of their products..

59. The information the drug company defendants disseminated to physicians concerning their metoclopramide products was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

60. As a foreseeable and proximate result of these breaches by the drug company defendants of their duty to exercise reasonable care, the plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when her physicians, in reasonable reliance upon the negligently inadequate information disseminated by the drug company defendants, prescribed for the plaintiff the use of metoclopramide products for a

prolonged and unwarranted period of time and she ingested, per those prescriptions, metoclopramide products manufactured by these defendants, leading to her toxic overexposure to metoclopramide.

FIFTH CAUSE OF ACTION
Products Liability - Negligence Per Se

61. Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

62. As part of their duty to exercise reasonable care for the safety of persons, including the plaintiff, who would be expected to use their products, the drug company defendants were obliged to follow laws and regulations enacted and promulgated to protect the safety of such persons, including, but not limited to, 21 U.S.C. §§ 331(a) and 352(a) and (f) and 18 V.S.A. §4052, which make it unlawful to misbrand prescription drug products.

63. The package inserts (and other consistent labeling, if any) for the metoclopramide products failed to conform to the requirements of 21 U.S.C. §§ 331(a) and 352(a) and (f) and 18 V.S.A. §§ 4052, inasmuch as the package inserts or other labeling contained false, inaccurate, misleading statements concerning the products' side effects and omitted information, including warnings and instructions for use, adequate to enable the use of the products in an ordinary, foreseeable, and intended manner that was reasonably safe, taking into account the potential benefits and potential risks entailed in such use.

64. In distributing the metoclopramide products labeled in violation of these statutes and regulations, each drug company defendant was negligent *per se*, as a matter of law.

65. As a foreseeable and proximate result of the negligence *per se* of the drug company defendants, specifically their violation of the above referenced statutes and regulations, the plaintiff suffered grievous bodily injury and consequent economic and other

loss, as described above, when her physicians, in reasonable reliance upon the information disseminated by the drug company defendants in violation of these statutes and regulations, prescribed for the plaintiff the use of metoclopramide products for a prolonged and unwarranted period of time and she ingested, per those prescriptions, metoclopramide products manufactured by these defendants, leading to her toxic overexposure to metoclopramide.

SIXTH CAUSE OF ACTION
Strict Products Liability

66. Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

67. The metoclopramide products, as distributed by the drug company defendants, were defective and unreasonably dangerous inasmuch as they were not accompanied by warnings and instructions that were appropriate and adequate to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of the products for long term metoclopramide therapy.

68. As a proximate result of these defects in the metoclopramide products which she ingested, and which had been manufactured, supplied, or sold in that defective and unreasonably dangerous condition by the drug company defendants, the plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above.

SEVENTH CAUSE OF ACTION
Products Liability - Breach of Express Warranties

69. Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

70. The Reglan and/or therapeutically equivalent generic metoclopramide products materially failed to conform to those representations which the several drug company defendants made, in package inserts and otherwise, concerning the properties and effects of the products which they manufactured and/or distributed and sold, and which the plaintiff purchased and ingested in direct or indirect reliance upon these express representations. That failure constituted a material breach of express warranties made, directly or indirectly, to the plaintiff, concerning the products thus sold to the plaintiff.

71. As a foreseeable and proximate result of these breaches of express warranties on the part of the drug company defendants, the plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when her physicians, in reasonable reliance upon these express warranties, prescribed for the plaintiff the use of metoclopramide products for a prolonged and unwarranted period of time and she purchased and ingested, per those prescriptions, metoclopramide products manufactured by these defendants, leading to her toxic overexposure to metoclopramide.

72. The plaintiff notified each of the the drug company defendants of the breaches of express warranties as soon as the breaches were ascertained and made known to her.

EIGHTH CAUSE OF ACTION
Products Liability - Breach of Implied Warranties

73. Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

74. Each of the drug company defendants severally and impliedly warranted the metoclopramide products which they manufactured and/or distributed and sold, and which the plaintiff purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the products were sold, including specifically long term metoclopramide therapy for the treatment of chronic and/or intermittent gastroesophogeal reflux and/or gastroporesis.

75. The drug company defendants breached their implied warranties of the metoclopramide products sold to the plaintiff, because these products were not of merchantable quality or fit for their common, ordinary, and intended use in long term therapy for the treatment of chronic and/or intermittent gastroesophogeal reflux and/or gastroporesis.

76. As a foreseeable and proximate result of these breaches of implied warranties on the part of the drug company defendants, the plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when her physicians, in reasonable reliance upon the implied warranties, prescribed for the plaintiff the use of metoclopramide products for a prolonged and unwarranted period of time and she purchased and ingested, per those prescriptions, metoclopramide products manufactured by these defendants, leading to her toxic overexposure to metoclopramide.

77. The plaintiff notified of the drug company defendants of the breaches of implied warranties as soon as the breach was ascertained and made known to her.

PRAYER FOR RELIEF

Plaintiff respectfully prays for relief against the defendants, and each of them, as follows:

1. General damages as allowed by law;

2. Special damages as allowed by law;

3. Costs of suit as allowed by law;

4. Attorneys' fees as allowed by law;

5. Prejudgment and postjudgment interest as allowed by law;

6. Punitive damages as allowed by law in an amount reasonably calculated to punish Defendants Wyeth, Purepac, Teva and Pliva and to deter others from engaging in similar conduct in the future; and

7. Such further or other relief, whether legal or equitable, as the Court deems proper.

JURY DEMAND

Plaintiff demands that all issues of fact in this case be tried to a properly empanelled jury.

Electronically executed this 3rd day of October, 2007.

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